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#### UNITED STATES PATENT AND TRADEMARK OFFICE

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# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

### *Ex parte* DAVID ERNEST HARTLEY

Application 10/647,642 Technology Center 3700

Decided: September 1, 2009

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Before ERIC GRIMES, FRANCISCO C. PRATS, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, Administrative Patent Judge.

#### **DECISION ON APPEAL**

This is an appeal under 35 U.S.C. § 134 involving a claim to a stent graft prosthesis. We have jurisdiction under 35 U.S.C. § 6(b). We affirmin-part.

Application 10/647,642

Statement of the Case

The Claims

Claims 1, 3, 4, 7-9, 11, 12, 15-19, and 22 are on appeal. Claims 1 and 3 have been argued separately. Claims 4, 7-9, 11, 12, 15-19, and 22 stand or fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

- A stent graft prosthesis mounted to a deployment 1. device and adapted to be deployed in a curved lumen, the curved lumen having an inner side and an outer side of the curve, the deployment device including a guide wire catheter, the stent graft prosthesis being temporarily mounted to the deployment device at at least one end of the prosthesis by a retention arrangement, the retention arrangement including a retention of the stent graft prosthesis to the guide wire catheter at a plurality of retention points of the circumference of the proximal end of the stent graft prosthesis, there being a greater circumferential distance between two adjacent retention points than other of the points, wherein the guide wire catheter includes a trigger wire catheter coaxially around the guide wire catheter with trigger wires passing along an annular space between the guide wire catheter and the trigger wire catheter and exiting through apertures in the trigger wire catheter at the retention points and the trigger wires are engaged with the graft material to provide the retention points and the apertures are equally spaced around the trigger wire catheter whereby when the deployment device is deployed in the curved lumen the greater circumferential distance is on the inner side of the curve.
- 3. A stent graft prosthesis mounted to a deployment device as in Claim 1 wherein the retention arrangement includes three retention points so that one larger and two smaller folds of the graft material are formed.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Chuter US 5,562,726 Oct. 8, 1996 Lau et al. US 5,873,906 Feb. 23, 1999

The issue

The Examiner rejected claims 1, 3, 4, 7-9, 11, 12, 15-19, and 22 under 35 U.S.C. § 103(a) as obvious over Lau and Chuter (Ans. 3-4).

The Examiner finds that "Lau discloses the invention substantially as claimed being a stent graft coupled to a deployment device through trigger wires that engage suture loops, which remain on the stent after deployment. However, Lau does not disclose that the trigger wires exit the catheter through separate apertures at the retention points" (Ans. 4). The Examiner finds that

Chuter teaches the use of a graft and a delivery system wherein the trigger wire is directed through two apertures (236) equally spaced about the catheter just prior to the engagement with the graft in the same field of endeavor for the purpose of providing a smooth path for both of the trigger wires to be moved without obstructing each other.

(Ans. 4.)

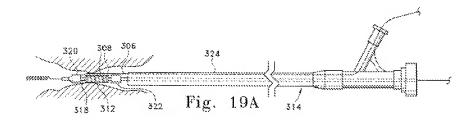
The Examiner finds that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the apertures taught by Chuter with the deployment device of Lau in order to keep the trigger wires untangled and separate from each other allowing a smoother release of the stent" (Ans. 4).

Appellant contends that "the combination of *Lau et al.* and *Chuter* fails to teach, either expressly or inherently, several of the elements recited in the rejected claims" (App. Br. 7). Appellant also contends that the Examiner "has combined the teachings of *Lau et al.* with *Chuter*. However, he has not articulated any reason why this combination would have been obvious" (App. Br. 9). Appellant also contends that "even if properly combined, *Chuter* does not make up the deficiencies in *Lau et al. Chuter* does not teach the differences in the circumferential distances at the proximal end of the prosthesis that would produce uneven lobes, and prevent a portion of the prosthesis to fold over during insertion" (App. Br. 9).

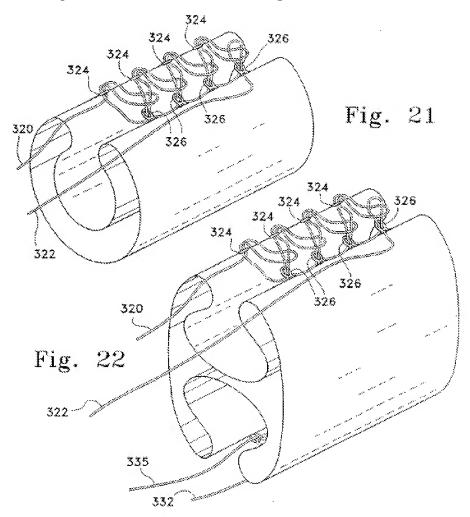
In view of these conflicting positions, we frame the obviousness issue before us as follows:

Has Appellant demonstrated that the Examiner erred in finding that the combination of Lau and Chuter render claims 1 and 3 obvious? *Findings of Fact (FF)* 

- 1. Lau teaches "a foldable stent or stent-graft which may be percutaneously delivered with (or on) a catheter, typically an endovascular catheter, to a body cavity or lumen" (Lau, col. 1, ll. 12-14).
  - 2. Figure 19 of Lau is reproduced below:



- "In FIG. 19A may be seen a percutaneous catheter assembly (314) which has been inserted into a selected site . . . within a body lumen" (Lau, col. 17, l. 66 to col. 18, l. 1).
- 3. Lau teaches that the "stent (312) is folded about the guidewire (319) and guidewire tube (318) held axially in place prior to deployment by distal barrier (320) and proximal barrier (322)" (Lau, col. 18, ll. 1-4).
  - 4. Figures 21 and 22 of Lau are reproduced below:



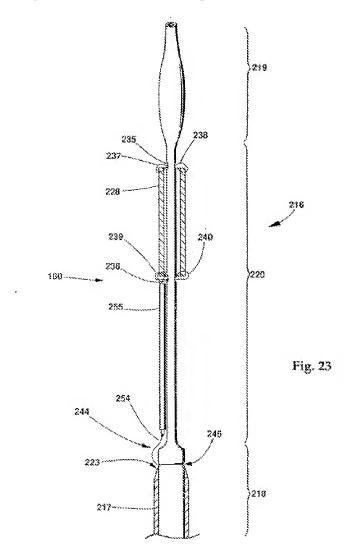
- "FIGS. 21 and 22 show front quarter views of folded stents or stent grafts held in that folded position by a tether wire using a sack knot" (Lau, col. 8, ll. 46-48).
- 5. Lau teaches that tetherwire 306 (shown in figure 19A) can be considered a "trigger wire" as recited in the claims because "removal of the tetherwire (306) from a portion of the loops (308) . . . partially expand[s] the stent (312) onto the selected site (316)" (Lau, col. 18, Il. 8-10).
- 6. Lau teaches a plurality of retention points with a trigger wire, noting that

the slip line has a fixed end (320) and a release end (322). [L]oops of the slip line pass through the eyelets (324) on the side of the stent fold associated with the fixed end (320) and are held in place by eyelets (326) on the side of the stent fold associated with the release end (322).

(Lau, col. 18, 11. 20-24.)

- 7. The Examiner finds that Lau teaches that "there is a greater circumferential distance between the retention points as shown in the figure below . . . the examiner maintains that the claims are broad enough to allow the interpretation of the lower two small flaps of Lau to be considered a single large lobe" (Ans. 6 (presenting an annotated version of Lau's Figure 22)).
- 8. Figure 22 of Lau shows retention points 324 and 326 on the upper side of the figure and unmarked retention points displayed at the bottom of figure 22 through which wires 335 and 332 pass. Retention points 324 and 326 are at a greater circumferential difference relative to the unmarked retention points than to each other (*see* FF 4).

- 9. The Examiner finds that "Lau does not disclose that the trigger wires exit the catheter through separate apertures at the retention points" (Ans. 4).
- 10. Chuter teaches "a transluminal graft prosthesis that can be safely and precisely positioned" (Chuter, col. 3, 11. 48-49).
  - 11. Figure 23 of Chuter is reproduced below:



"FIG. 23 depicts a carrier" (Chuter, col. 6, 1. 65).

- 12. Chuter teaches that "[d]uring insertion, prosthesis 228 and its associated catheter systems are compressed into the space between introducer sheath 217 and carrier stem 220" (Chuter, col. 16, ll. 21-24).
- 13. Chuter teaches that "[a]s depicted in FIG. 23, two pairs of holes 235 and 236 traverse the outer catheter of the carrier stem, one pair at each end of prosthesis 228" (Chuter, col. 16, ll. 25-27).
- 14. Chuter teaches that "small loops of suture 237 and 238 wind around inner catheter 229 at this point, entering and exiting the lumen of outer catheter 230 through the holes" (Chuter, col. 16, 11, 27-30).
- 15. Chuter teaches that "[t]hese sutures, as well as suture loops 239 and 240, also traverse some part of prosthesis 228, thereby attaching both ends of the prosthesis to the central carrier. Loops 237-240 (and the prosthesis) are released by removal of inner catheter 229" (Chuter, col. 16, 11. 30-34).
- 16. Chuter teaches that "[i]t is important that the two loops of each set do not cross, otherwise the resulting linkage will prevent release from the central carrier despite removal of the inner catheter" (Chuter, col. 16, ll. 34-37).

## Principles of Law

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). "If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id.* at 417. Moreover, an "[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution

obvious." *In re Fout*, 675 F.2d 297, 301 (CCPA 1982). As noted by the Court in *KSR*, "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." 550 U.S. at 421.

"[T]he PTO gives a disputed claim term its broadest reasonable interpretation during patent prosecution." *In re Bigio*, 381 F.3d 1320, 1324 (Fed. Cir. 2004). The court recognizes the fairness of reading claims broadly "before a patent is granted [since] the claims are readily amended as part of the examination process." *Burlington Indus., Inc. v. Quigg*, 822 F.2d 1581, 1583 (Fed. Cir. 1987). "Thus, a patent applicant has the opportunity and responsibility to remove any ambiguity in claim term meaning by amending the application." *Bigio*, 381 F.3d at 1324. Applying the broadest reasonable interpretation to claims also "serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified." *In re Am. Acad. Of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

Analysis

#### Claim 1

Lau teaches a stent graft and deployment device where the deployment device includes a guide wire catheter (FF 1-3). Lau teaches that the stent graft is mounted with a retention arrangement at a plurality of retention points (FF 4-6). While Lau does not teach that the trigger wires exit through apertures in the trigger wire catheter (FF 9), Chuter teaches a catheter in which the trigger wires exit through such apertures to prevent linkage or tangling (FF 10-16).

We are not persuaded by Appellant's argument that "the configuration of the tether wire of *Lau et al.* does not produce the 'a greater circumferential distance between two adjacent retention points than other of the points" (App. Br. 8). We note that claim 1 relates the retention points to "other of the points" and imposes no further requirement on the circumferential difference. Figure 22 of Lau shows retention points 324 and 326 on the upper side of the figure and unmarked retention points displayed at the bottom of figure 22 through which wires 335 and 332 pass. Retention points 324 and 326 are reasonably interpreted as being at a greater circumferential difference relative to the unmarked retention points than to each other (*see* FF 4, 6-8).

We are not persuaded by Appellant's argument that "Lau et al. discloses a tether wire that laces around the <u>outside</u> of the prosthesis, and is not connected to a trigger wire catheter" (App. Br. 7). Appellant also contends that the "circumferentially spaced points along the length of the prosthesis in Lau et al. are connected to each other and not to a delivery device" (App. Br. 7-8). We agree with the Examiner that claim 1 "never recite[s] that the trigger wire is connected to the delivery device" (Ans. 4). We also agree with the Examiner that the claim requirement is that "the trigger wires passes through apertures in the delivery device" (Ans. 5). As the Examiner correctly notes, the "modification of Chuter adds the apertures to the delivery device of Lau in order to guide the trigger wires" (Ans. 5; FF 10-16). We think that the rejection clearly relies on Chuter to satisfy the requirements for the location of the trigger wires "passing along an annular

space between the guide wire catheter and the trigger wire catheter" (FF 10-16).

We are also not persuaded by Appellant's argument that "Lau et al., does not show the retention of the <u>proximal</u> end of the prosthesis by the deployment device" (App. Br. 8). As Appellant acknowledges in the Reply Brief, "Applicant agrees with the Examiner that the proximal end, as shown in Lau, is actually the distal end" (Reply Br. 1-2). We agree with the Examiner that the "wires extend distally to the back of the delivery device of Lau" (Ans. 5), as shown in figure 22 of Lau (FF 4).

Finally, we are not persuaded by Appellant's argument that the Examiner "has not articulated any reason why this combination would have been obvious" (App. Br. 9). The Examiner explained that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the apertures taught by Chuter with the deployment device of Lau in order to keep the trigger wires untangled and separate from each other allowing a smoother release of the stent" (Ans. 4). The Examiner provides a specific reason, including a motivation in Chuter for modifying Lau with the apertures of Chuter, satisfying not only the requirements of obviousness under *KSR*, but reasonably providing a specific motivation as well.

## Claim 3

Appellant argues that "dependent claim 3 further requires that the retention arrangement include 'three retention points so that one larger and two smaller folds of the graft material are formed" (App. Br. 10).

Appellant argues that Lau and Chuter do not disclose this element (*see* App. Br. 10).

The Examiner finds that Lau teaches that "[t]he retention device forms 3 lobes. There are two small upper lobes formed by upper retention points (324) and (326) and one large lower lobe shown in figure 22 and again in the figure below for more clarity" (Ans. 3-4).

We think that Appellant has the better argument. Figure 22 of Lau might reasonably be interpreted as showing four equal lobes or even as showing two equal lobes (where the two sides were each lobes), but it is not a reasonable interpretation of the figure to interpret the upper half as having two lobes and the lower half as being composed of a single lobe. No other evidence or reason to suggest that the "three retention points so that one larger and two smaller folds of the graft material are formed" as claim 3 requires is presented. We therefore find that the combination of Lau and Chuter does not render claim 3 obvious.

## Conclusions of Law

- (i) Appellant has not demonstrated that the Examiner erred in finding that the combination of Lau and Chuter renders claim 1 obvious.
- (ii) Appellant has demonstrated that the Examiner erred in finding that the combination of Lau and Chuter renders claim 3 obvious.

#### **SUMMARY**

In summary, we affirm the rejection of claim 1 under 35 U.S.C. § 103(a) as obvious over Lau and Chuter. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 4, 7-9, 11, 12, 15-19, and 22, as these claims were not argued separately.

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We reverse the rejection of claim 3 under 35 U.S.C. § 103(a) as obvious over Lau and Chuter.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

# **AFFIRMED-IN-PART**

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